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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/040,161	03/17/98	KORNB LITH	2509-980383

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EXAMINER

GITOMER J, A

ART UNIT	PAPER NUMBER
1623	5

DATE MAILED: 10/13/98

**Please find below and/or attached an Office communication concerning this application r proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/040,161

Applicant(s)  
K rnbllth

Examiner  
Ralph Gitomer

Group Art Unit  
1623



☒ Responsive to communication(s) filed on Sep 8, 1998

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 13-20 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 13-20 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The amendment and Terminal Disclaimer received 9/8/98 have been entered and claims 13-20 are currently pending in this application.

5           Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The feature of the size of the particulates is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. *In re Mayhew*, 527  
10 F.2d 1229, 188 USPQ 356 (CCPA 1976).

          On page 5 lines 15-16 of the present specification, "Preferably but not necessarily, the tumor particulates each measure 1 mm3." It would appear the claimed invention would not work unless the particulates were of a certain size and the  
15 specification teaches only this one size.

          Claims 13-20 are rejected under 35 U.S.C. 112, first  
20 paragraph, because the specification, while being enabling for particles of a specific size, does not reasonably provide enablement for particles of any size. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the  
25 invention commensurate in scope with these claims.

In claim 13 and all occurrences, the terms "cohesive multicellular particulates" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which size would work in the instant invention.

5 "Cohesive multicellular particulates" reads on an entire organ to two cells, neither of which are likely to work in the claimed invention. The addition to the claims of "having smooth cut edges" does not in any fashion distinguish the size of the particulates. And referring to minced tumor tissue, although  
10 indefinite regarding size, refers to very small samples.

Note this examiner was employed in a pathology lab where most of the samples he received were severed heads, either complete or portions thereof. Virtually all of the samples has at least one smooth cut edge at the neck where the specimen was  
15 prepared and most of the samples had some region of minced tissue, generally where an injury occurred such as a bullet exit wound. Most of the heads weighed 10-12 pounds, were cohesive multicellular particulates, had smooth cut edges and had minced tissue. And possibly some of the heads had tumor tissue which  
20 would then read on the presently claimed samples directly.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large number of sizes claimed.

2. Amount of direction or guidance presented is insufficient to  
25 predict which sizes encompassed by the claims would work.

3. Presence of working examples are only for a single size and extension to other sizes has not been specifically taught or suggested.

4. The nature of the invention is complex and unpredictable.

5 5. State of the prior art indicates that most sizes are not effective for the claimed functions.

6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of sizes.

10 8. The level of one of ordinary skill in this art is variable.  
In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Applicant's arguments filed 9/8/98 have been fully considered but they are not persuasive.

15 Applicant argues that the specification uses minced as cut or chop into very small pieces and smooth cut edges eliminates microscopic size particles.

It is the examiner's position that not all the claims contain the term "minced" and minced is not specific to size.  
20 Subcellular fractions can be cut into microscopic particles with smooth cut edges and this examiner has performed this act in a pathology lab.

Claims 13-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 In claim 13, "cohesive multicellular particulates" is not understood as so what the specimen is separated into. Note the expression reads on no separating to forming two cell particulates.

10 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of  
15 the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing  
20 date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Art Unit 1623

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.

5 The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this  
10 application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

15

  
Ralph Gitomer  
Primary Examiner  
Group 1623

RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200